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510(k) Summary

APPLICANT
Hemostasis, LLC Corporation
5000 Township Parkway, St. Paul, MN 55110
Telephone: 651-855-1466
Fax: 651-651-855-1465
Contact: Keith Roberts
Title: Technical Business Development

Company Name: Hemostasis, LLC

Classification Name: Dressing, Unclassified, Product Code – FRO

Common/Usual Name: Topical hemostatic particles and foam

Proprietary Name: TraumArrest™ (Rx) particle and foam and BleedArrest (OTC) particle and foam.

Establishment Registration Number and Manufacturing Location: To be Assigned Hemostasis, LLC is located at 5000 Township Parkway, St. Paul, MN 55110.

Performance Standards: N/A

Substantial Equivalence: The Hemostasis, LLC TraumArrest™ and BleedArrest particles and foam are substantially equivalent to the Medafor HemaDerm and Bleed-X products which were the subject of premarket notification numbers K033666 and K013225. Hemostasis, LLC believes we have demonstrated that our hemostat devices have performed as well as the above predicate devices. A list of additional predicate devices including their subsequent labeling claims is provided in the summary table titled Matrix of Predicate Devices in Section 12.

COMPARATIVE TESTING OF SUBSTANTIALLY EQUIVALENT DEVICES
Hemostasis, LLC has performed biocompatibility testing on our devices as well as comparative testing using a Porcine Model.

DESCRIPTION
As described above, the Hemostasis, LLC hemostats are comprised of plant based starch particles. The particles consist in two forms; one is starch particles and one is starch particles processed into a foam using a lyophylization process and include a polysaccharide binder hydroxypropylmethylcellulose (HPMC). Starch is a polysaccharide that is a well known hemostatic agent due to its ability to hold moisture. The Hemostasis hemostatic particles and foam quickly dehydrate blood cells, thereby causing rapid hemoconcentration of platelets, serum proteins and fibrinogen, leading to clotting that limits and controls bleeding in moderate to severe lacerations.

INDICATIONS FOR USE

The Hemostasis, LLC wound dressings are intended for use as topical dressings for the management of bleeding wounds.

Prescription: TraumArrest™ is indicated for use as a topical dressing for the temporary treatment of moderate to severely bleeding wounds such as surgical wounds (post-operative, donor sites, dermatological), cuts and lacerations and is also indicated for control of bleeding from the skin at percutaneous needle access, vascular access and percutaneous catheter access sites.

OTC: BleedArrest™ particles and foam are indicated for use as a topical dressing on minor bleeding wounds such as cuts, lacerations and abrasions and for minor nose bleeds.

PREDICATE DEVICE
Medafor HemaDerm and Bleed-X products which were the subject of Premarket Notification numbers K033666 and K013225.

BIOCOMPATIBILITY
The classification and applicable testing of the Hemostasis devices were determined using guidelines of ISO 10993 – Biological Evaluation of Medical Devices and FDA guidance document Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices May 1, 1995 (G95-1). The criteria have been satisfied for biocompatibility.

PORCINE MODEL FOR COMPARATIVE PERFORMANCE TESTING
Comparative testing was performed using a Porcine Model and the devices met the performance criteria.

The Hemostasis, LLC products will be provided sterile.

CONCLUSION

Through the data and information presented, Hemostasis, LLC considers the devices substantially equivalent to legally marketed predicated devices cited in this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 5 - 2007

Hemostasis, LLC
% Mr. Keith A. Roberts
5000 Township Parkway
St. Paul, Minnesota 55110

Re: K070211
Trade/Device Name: TraumArrest™ and BleedArrest
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 16, 2007
Received: January 22, 2007

Dear Mr. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use/ Indications for Use

510(k) Number (if known): K070211

Device Name: Indications for Use:

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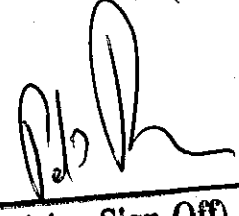
OTC: BleedArrest™ particles and foam are indicated for use as a topical dressing on minor bleeding wounds such as cuts, lacerations and abrasions and for minor nose bleeds.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070211